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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/056,019	04/07/1998	ELAINE I. TUOMANEN	44158/207989(5853-2)	4774

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/056,019	TUOMANEN ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on CPA filed 06/07/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-94 is/are pending in the application.
- 4a) Of the above claim(s) 53, 64, 73, 80 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46, 47, 50-52, 54-63, 65-72, 74-79, 81-89 and 91-94 is/are rejected.
- 7) ☒ Claim(s) 48 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Prosecution Application

The request filed on 6/7/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/056,019 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-45 have been cancelled and claims 46-94 newly introduced.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Newly submitted claims 53, 64, 73, 80, and 90 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Polypeptide vaccine claims properly correspond to group V, claims 42-43, in the original restriction requirement (Paper No. 10). This invention was not elected.

Claim 73 is specifically directed to a vaccine.

Claims 64 and 90 are directed to a polypeptide "immunogenic against bacterial infection." While the claims do not use the term "vaccine" this appears to be the intent of the claim.

Claims 53 and 80 are directed to a pharmaceutical composition. The use of the term "pharmaceutical" in the preamble and the absence of a particular intended use in the body of the claim requires that all intended uses be enabled. As such, these claims also encompass polypeptide vaccines.

These claims are contrasted with claims 50, 56, 77, and 83 where the "polypeptide is immunogenic." The specification does not appear to provide a specific definition of what was intended to be encompassed. The broadest reasonable interpretation of "immunogenic" includes the ability to raise an antibody against the recited polypeptide. As such, these claims are not considered to be directed to vaccines.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53, 64, 73, 80, and 90 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. The abstract submitted in the response has not been entered as it is not on a separate sheet.

The disclosure is objected to because of the following informalities: The description of Figure 2A does not provide a SEQ ID NO. for each of the sequences depicted. Note that there are thirteen sequences shown in the figure and only twelve reference numbers are provided. The first sequence (at the top of the Figure) previously was identified as corresponding to the sequence of SEQ ID NO: 24. This was clearly erroneous as the first sequence of the figure begins AVASL whereas SEQ ID NO: 24 begins Glu Asn Glu Gly (ENEG). Applicant is again

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requested to verify that the remaining sequences do in fact correspond to SEQ ID NO: 28-39 and to identify which SEQ ID NO. corresponds to the first sequence.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 51, 57-63, 65-68, 71-72, 79, 84-89, and 91-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 51, 57, 78, and 84 recite "up to 475 amino acids." Basis is stated to be on page 7, lines 3-5; however, this concept is not set forth here. Only a particular protein of 475 amino acids is disclosed. Note that these claims are confusing in that SEQ ID NO: 5 is 109 amino acids and it is unclear whether the dependent claims are directed to fragments of SEQ ID NO: 5 or larger proteins containing SEQ ID NO: 5. Likewise, SEQ ID NO: 4 is only 106 amino acids, SEQ ID NO: 11 is only 107 amino acids, and SEQ ID NO: 10 is only 106 amino acids.

Claims 52, 58, 79, and 85 recite "up to 460 amino acids." Basis is stated to be on pages 6 and 37 and Figure 2B; however, this concept is not set forth here. Note that these claims are confusing in that SEQ ID NO: 5 is 109 amino acids and it is unclear whether the dependent claims are directed to fragments of SEQ ID NO: 5 or larger proteins containing SEQ ID NO: 5. Likewise, SEQ ID NO: 4 is only 106 amino acids, SEQ ID NO: 11 is only 107 amino acids, and SEQ ID NO: 10 is only 106 amino acids.

Claim 59 recites a fragment of "at least 52 consecutive amino acids" of SEQ ID NO: 24. Basis is stated to be on page 6, line 15; however, this concept is not set forth here. Only conservative regions are disclosed. See also claim 86.

Claim 60 recites "at least one to 57 amino acid substitutions." Basis is stated to be on pages 13-14; however, this concept is not set forth here. Only particular amino acid substitutions are disclosed. See also claims 61-63, 67-68, 87-89, and 93-94 and dependent claims.

Claims 65 and 91 recite "host preferred amino acid substitutions." Basis is stated to be on page 13; however this concept is not set forth here. Only codons preferred for expression in selected non-mammalian hosts.

Claims 71-72 recite "retains native tertiary structure" with respect to all of the named SEQ ID NOS. Basis is stated to be on page 7, lines 6-8. The specification provides no disclosure of this concept nor what the native tertiary structure is for each of these polypeptides.

Claims 69-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide any guidance on how to determine tertiary structure (e.g. X-ray crystallography) or how to identify different tertiary structures encompassed by the claims (folded, unfolded, misfolded). With respect to claims 71-72, this claim language does not exclude other tertiary structures that the native protein may take under different conditions. In addition binding proteins routinely change tertiary structure upon binding to a ligand. The

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specification disclosure is directed more to retaining a particular function than retaining a particular structure. As such, the specification enables production of the protein which inherently possesses a particular tertiary structure (which is not elaborated upon) but does not enable producing proteins with other unspecified tertiary structures.

The specification does not appear to define the metes and bounds of an "analog" or "derivative." As such, one of ordinary skill in the art would not know what polypeptide to make with respect to claims 69 and 70.

Claims 55 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is confusing in reciting "comprising SEQ ID NO: 22" and being dependent upon claim 54 which comprises "SEQ ID NO: 4." SEQ ID NO: 22 does not encompass SEQ ID NO: 4.

Claim 82 is confusing in reciting "comprising SEQ ID NO:23" and being dependent upon claim 81 which comprises "SEQ ID NO: 10." SEQ ID NO: 23 does not encompass SEQ ID NO: 10.

Claims ^{46-47, 50-52}~~46-52~~, 54-63, 65-72, 74-79, 81-89, and 91-94 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: inclusion of entirety of sequence responsible for lectin activity.

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Page 62 of the specification states that SEQ ID NO: 1 (406 amino acids) is required for lectin activity. The claims include shorter sequences that must possess the recited lectin activity. There is no evidence of record that the shorter fragments possess lectin activity.

Claim Rejections - 35 USC § 102

Claims 69-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Masure et al. (WO 97/41151).

SEQ ID NO: 25 of Masure et al. is disclosed as the amino acid sequence of a choline binding protein from Streptococcus pneumoniae. The sequence listing identifies it as an N-terminal fragment. The reference discloses fragments and pharmaceutical compositions (including immunogenic vaccines) of the disclosed CBPs. This sequence has two N-terminal methionines. (See at least abstract, page 50, sequence listing, and claims.) SEQ ID NO: 25 has sequence in common with SEQ ID NOS: 1, 3, 7, and 9 of the instant invention and has the motif of SEQ ID NO: 6 (KXXE). Claim 69 is directed to an analog and claim 70 is directed to a derivative of the named SEQ ID NOS. but have no particular structural requirements. As such, SEQ ID NO: 25 and the disclosure of Masure et al. properly anticipate the claims. The reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met. Note that the specification does not specifically define an analog or derivative.

Claims 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Briles et al. (WO 97/09994).

The protein sequences disclosed by Briles et al. are disclosed as from Streptococcus pneumoniae and include N-terminal fragment. Many have N-terminal methionines. The reference discloses fragments and pharmaceutical compositions (including immunogenic vaccines) of the disclosed proteins. (See at least abstract, claims, and Figures 13, 21, and 22.) These sequences have sequence in common with SEQ ID NOS: 1, 3, 7, and 9 of the instant invention and have the motif of SEQ ID NO: 6 (KXXE). Claim 69 is directed to an analog and claim 70 is directed to a derivative of the named SEQ ID NOS. but have no particular structural requirements. As such, SEQ ID NO: 25 and the disclosure of Masure et al. properly anticipate the claims. The reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met. Note that the specification does not define the metes and bounds of an analog or derivative.

Claims 69-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Hammerschmidt et al. (Molecular Microbiology, 1997).

The sequence for type 47 in Figure 9 of Hammerschmidt et al. has the motif of SEQ ID NO: 6 (KXXE) and contains SEQ ID NO: 9. The figure description identifies it as an N-terminal fragment with an N-terminal methionine. Compositions in pharmaceutically acceptable carriers are disclosed. (See at least abstract and Figure 9.) Claim 69 is directed to an analog and claim 70 is directed to a derivative of the named SEQ ID NOS. but have no particular structural requirements. As such, SEQ ID NO: 25 and the disclosure of Masure et al. properly anticipate the claims. The reference is silent as to lectin activity and choline binding properties; however,

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absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met. Note that the specification does not specifically define an analog or derivative.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
August 16, 2002